REMARKS

Although not necessary for patentability, claim 5 has been canceled, in the interest of progressing this case to issuance without delay, and to make it clear that the retinoid stabilization system of the present invention is completely different from that of Habif et al. and Simon, as reflected in the claims and discussed in more detail hereinbelow. The present retinoid stabilization system does not require crystalline fatty acid. The barrier in Habif et al., intended to prevent water from getting into the retinoid phase and retinoid from getting into the water phase is not necessary for the present invention. According to the present invention, the polymeric emulsifiers serve the function of preventing water from entering the retinoid phase and vice-versa, thereby advantageously achieving retinoid stability of as high as at least 70 days at 50 C, which is greater than that possible according to Habif et al.

The Present Invention

Retinoids are known to be unstable and this is the problem addressed by the present invention. The present invention is directed to stabilization of Retinoids in water-in-oil-emulsions. The unique system consisting of, as essential components, a retinoid solubilized in a fluid oil, in combination with a polymeric emulsifier selected from the group consisting of an amphipathic block co-polymer and/or polymer containing a hydrophilic backbone modified

with hydrophobic groups enables greater Retinoid stability than previously possible. A Retinoid half-life as long as at least 70 days at 50 C is advantageously achievable according to the present invention.

Claims 1-12 Are Not Obvious Under 35 USC § 103 Over Habif et al. (EP 832 643) in view of Simon (US 6,346,256)

According to the Office Action, Habif et al. disclose the stabilization of an unstable retinoid in oil-in-water emulsion for skin care compositions.; Exemplified is a composition comprising 3% butylene glycol-1,3 (humectant), stearyl alcohol (fluid oil alcohol), stearic acid (crystalline fatty acid), isostearyl palmitate (fluid oil), dimethicone (volatile silicone), linoleamide (retinoid booster) and 0.29% retinol.; The compositions of the invention preferably have a half-lifetime of from 20-45 days at 50°C, and the fluid oil must be capable of solubilizing, at a storage temperature (25°C), the required amount of retinol or esters thereof.; Simon teaches Pemulen TR2 (a polymer containing a hydrophilic backbone modified with hydrophobic groups) as stabilizing oil-in-water emulsions.

The Office Action concludes that, it would have been obvious to one or ordinary skill in the art at the time the invention was made to add Pemulen TR2 to the oil-in-water emulsions of Habif et al. because of the <u>expectation of achieving a highly stable emulsion</u> (emphasis added, distinguished below).

Further according to the Office Action, while the reference does not teach the half-life of the retinoid in the composition of about 70 days at 50°C

or the actual amount of grams of retinoid soluble per grams of oil, the composition of the combined references must have these properties, since the combined references teach the composition of the instant invention.; For the purposes of searching for and applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to comprising.; If an applicant contends that additional steps or material in the prior art are excluded by the recitation of "consisting essentially of", applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention.

Applicants respectfully traverse the rejection. As previously established (with reference to mootness of the earlier rejection), Habif stabilize retinoids in a different way than the present invention. Habif do not stabilize retinoids to as great a degree as the present invention. The present invention excludes crystalline fatty acid and barrier ingredient, rather achieving retinoid stability with the specified polymeric emulsifier system. There would be no motivation for one skilled in the art to look to Simon for stabilizing retinoids as Simon has nothing to do with retinoids. One skilled in the art with the goal of stabilizing retinoids would not be motivated to look to Simon, which discusses stabilizing emulsions.

Furthermore, Claim 1 excludes the crystal sizing component, which is essential to the barrier component in the composition of Habif et al. See

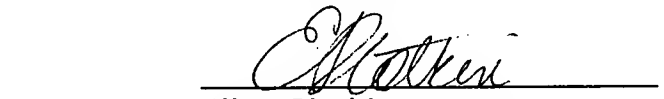
Habif et al. Claim 1. In other words, Applicants' composition excludes as essential components hydroxyethylated fatty acids or alcohols (C12-C22) and ethoxylated derivatives thereof. Compare Habif et al., page 4, lines 4-7 (stating that the barrier ingredient is essential to the emulsions of Habif); Claims 1 and 3; p. 3, lines 28-33. In fact, Habif teach away from the present invention, as Applicants are able to achieve retinoid stability in the absence of the crystal sizing component. Accordingly, Applicants respectfully submit that their composition is materially different from that of Habif and from Habif in combination with Simon (assuming there were motivation to combine the references, which Applicants submit there is not).

The basic and novel characteristics of the present invention are set forth in the independent claim 1, as well as in the Specification.

The present invention is directed to a superior alternative system for stabilizing retinoids in the composition.

In view of the foregoing amendment and comments, applicants request the Examiner to reconsider the rejection and now allow the claims.

Respectfully submitted,



Ellen Plotkin
Registration No. 36,636
Attorney for Applicant(s)

(201) 840-2253

E:\data\word\patents\RetinoidBoosters\J6656\J6656AmdAF 9-19-03.doc